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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,687	12/28/2005	Shigeto Uchiyama	Q92435	3798

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,687	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 12/4/09 is acknowledged.

Claims 1-8 and 13 are being considered on the merits. Claims 9-12 are withdrawn from consideration as directed to a non-elected invention.

The rejection under 35 U.S.C 112, regarding deposit is withdrawn in view of applicant's averments.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Setchell *et al.* (U.S. Patent No. 7,396,855).

The claims are directed to a composition comprising a strain of *Lactococcus* which is equol-producing as an essential component.

Setchell *et al.* disclose a composition comprising a strain of *Lactococcus* which is equol-producing as an essential component . See, e.g., Example 5, which contains soy milk, daidzein and equol.

It is noted that neither the amount of equol nor the amount of *Lactococcus* contained in the composition as claimed.

Therefore, the invention is anticipated by the reference.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Setchell nowhere discloses that daidzein can be converted into equol using these six strains singly. However, the claimed invention is directed to a composition that comprises "as an essential component" an undefined amount of an unidentified strain of *Lactococcus* that "has an ability to utilize" at least one of various compounds "to produce equol".

It is noted that the amount of daidzein, the amount of *Lactococcus* or the amount of equol contained in the composition are not claimed. In addition, it is also noted that in claim 7 equol is part of the original composition. It can reasonably be presumed that *Lactococcus* has an ability to produce equol as claimed, particularly in the absence of evidence to the contrary..

Applicant has not shown with objective evidence that the strain of Setchell is incapable of utilizing at least one of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol.

Therefore, it is submitted that the reference anticipates the invention as claimed.

Claims 1-8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Setchell *et al.* (U.S. Patent No. 7,396,855) taken with Elliott *et al.*, of record.

The claims are directed to a composition comprising a strain of *Lactococcus* which is equol-producing as an essential component.

Setchell *et al.* disclose a composition comprising a strain of *Lactococcus* which is equol-producing as an essential component . See, e.g., Example 5, which contains soy milk, daidzein and equol. It is noted that neither the amount of equol nor the amount of *Lactococcus* contained in the composition as claimed.

The reference differs from the invention as claimed in that the strain disclosed by Setchell *et al.* is classified as *L. lactis* rather than *L. garvieae* has not been given the same deposit number. However, Elliottt *et al.* adequately demonstrate that the classification boundaries between as *L. lactis* and *L. garvieae* are not clearly defined. The close taxonomic status

demonstrates that the species are clearly closely related, as evidenced also by their capabilities regarding the biotransformation of daidzein and related compounds into equol in compositions such as milk, and soy milk in particular.

With regard to the specific strain included in the composition, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share, such as belonging to the same genus *Lactococcus* and producing equol.. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious at the time the claimed invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that Setchell nowhere discloses that daidzein can be converted into equol using these six strains singly. However, the claimed invention is directed to a composition that comprises "as an essential component" an undefined amount of an unidentified strain of *Lactococcus* that "has an ability to utilize" at least one of various compounds "to produce equol".

It is noted that the amount of daidzein, the amount of *Lactococcus* or the amount of equol contained in the composition are not claimed. In addition, it is also noted that in claim 7 equol is part of the original composition.

In addition, applicant has not shown with objective evidence that the strain of Setchell is incapable of utilizing at least one of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol.

Regarding the lack of disclosure in Setchell of *L. garvieae* FERM BP-10036, it is emphasized that the depository identification is not an inherent property of a given strain. It is noted that strains are often re-deposited and identical strains may have several deposit accession numbers from the same or different depositories. Moreover, not all attributes of a given strain

are necessarily disclosed in a reference. This does not mean that they are lacking or different from a strain of interest.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent, from the strains discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art strain, which is of the same genus *Lactococcus* as that claimed, and likewise appears to share the property of being able to produce equol, she has reasonably demonstrated a reasonable likelihood/possibility that the compared strains are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

nAny inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651